AUDIT REPORT FOR HONDURAS MARCH 21 THROUGH MARCH 29, 2000

January 17, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Honduras' meat inspection system from March 21 through March 29, 2000. Two establishments seeking certification to export meat to the United States were audited. Both of these were slaughter and boning establishments.

The last audit of the Honduran meat inspection system was conducted in October 1997. Five establishments were audited: three were acceptable (8, 9, 12), one was evaluated as acceptable/re-review (4), and one was unacceptable (7). The major concerns of this review were: Update the boneless meat reinspection criteria and documents to reflect the zero-tolerance for ingesta and ensure that the establishment assume responsibility for boneless meat reinspection and that in-plant inspection personnel verify the establishment's activities, ensure that the written *E.coli* sampling program and SSOP meet U.S. requirements, and also make sure that in-plant inspection personnel verify and validate the establishment's compliance with the SSOP.

The only fresh product eligible for export to the United States is beef. Pork and poultry must be cooked to be eligible for export to the United States. During calendar year 1999, Honduran establishments exported around one million pounds of beef to the U.S. There were no port-of-entry rejections. There have been no exports to the U.S. during year 2000.

PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with Honduran national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second was conducted by on-site visits to establishments. The third was a visit to a laboratory that performs analytical testing of field samples for the national residue testing program, and the culturing of field samples for the presence of microbiological contamination with *Salmonella*.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including

the testing program for *Salmonella* species. Honduras' inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Based on the performance of the individual establishments, Honduras' "In-Plant Inspection System Performance" was evaluated as In-Plant System Controls In Place.

Effective inspection system controls were found to be in place in both establishments audited. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli* are discussed later in this report.

Entrance Meeting

On January 20, an entrance meeting was held at the Tegucigalpa offices of the Honduran National Service of Animal and Plant Health (SENASA), and was attended by Dr. Francisco Rodas, Sub-Director of SENASA; Dr. Pedro Mendoza, Chief of Official Inspection Service of Animal Products (SIOPOA); Dr. Alberto Cruz, National Supervisor of SIOPOA; Dr. Francisco Ordonez, Regional Supervisor of SIOPOA; Dr. Pedro Barahona, Chief of Meat Section of SIOPOA; Dr. Max Rivera, Director of National Residue Laboratory (ANEDEC); Mr. Raul Saybe, Chief of Dairy Section of SIOPOA; Ms.Gloria De Guzman, Translator; Mr. Omar Gonzales, Agriculture U.S. Embassy and Dr. M.Douglas Parks, International Auditor, USDA. Topics of discussion included the following:

- 1. Compliance and enforcement
- 2. Inspection Service training
- 3. Various requests from USDA Policy, e.g. species testing, residue questionnaire, microbiology testing, and laboratory responsibilities.
- 4. On-site visits and in-plant records audit.
- 5. Itinerary

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Honduras' inspection system in October 1997. To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

Since there are only two establishments seeking U.S. Certification, both establishments were visited and the records were audited at the same time as the on-site visit. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were seeking certification to export to the U.S.
- Training records for inspectors and laboratory personnel.
- Label approval records such as generic labels.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

No concerns arose as a result the examination of these documents.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Honduras as eligible to export meat products to the United States were full-time SENASA employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Two establishments were seeking certification to export meat and meat products to the United States at the time this audit was conducted. Both establishments were visited for onsite audits. In both of the establishments visited, both SENASA inspection system controls

and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audit, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

- 1. Government oversight of accredited, approved, and private laboratories.
- 2. Intra-laboratory quality assurance procedures, including sample handling.
- 3. Methodology.

The Residue National Laboratory (ANEDEC) in Tegucigalpa was audited on March 27, 2000. Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done.

The check sample program did meet FSIS requirements. In most sections of the laboratory, spiked samples were routinely run and were considered to be check samples.

Honduras' microbiological testing for *Salmonella* was being performed in this government laboratory. One of these, the Laboratorio Nacional De Analsis De Residuos Quimicos y Microbiologicos (LANAR)was audited. These criteria are:

- 1. The laboratory was accredited/approved by the government.
- 2. The laboratory had properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
- 3. Results of analyses were being reported simultaneously to the government and establishment.

Establishment Operations by Establishment Number

The following operations were being conducted in the two establishments:

Beef slaughter and boning – two establishments (4 and 12)

SANITATION CONTROLS

Based on the on-site audits of establishments, Honduras' inspection system had controls in place for the following:

- 1. Contamination control
- 2. Disease control
- 3. Residue control

- 4. Processed product control
- 5. Compliance/Economical Fraud control

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements, with only occasional variations.

Cross-Contamination

Variations of Sanitary dressing procedures were noted in establishment 12 as follows: A few beef tails, ready to be shipped and stored in the product cooler, were contaminated with feces and multiple hairs; beef esophagi that were ready to be packed, were not split open completely, thus providing high probability of unseen ingesta; skin flaps from the neck were reflected and held up by a skin penetrating hook higher on the neck

Product Handling and Storage

Boxed product destined for domestic or export sales were not marked as such and were stored in the same freezer in establishment 4. An edible product recovery tray with holes, located under a conveyor belt, was placed directly on the floor, and a product box, ready for use, was stained with blood and residues from the previous day's use in establishment 12.

ANIMAL DISEASE CONTROLS

Honduras' inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

RESIDUE CONTROLS

Honduras' National Residue Testing Plan for 2000 was being followed, and was on schedule. The Honduran inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

Except as noted below, the Honduran inspection system had controls in place to ensure adequate humane slaughter, slaughtering, processing (boning and cutting), packaging and storage of product.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements.

Testing for Generic E. coli

Honduras has adopted the FSIS regulatory requirements for E. coli testing.

Both of the establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The E. coli testing programs were found to meet the basic FSIS regulatory requirements.

Additionally, establishments had adequate controls in place to prevent meat products intended for Honduran domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

The SENASA inspection system controls [ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock or poultry from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other counties for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and

properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for Salmonella Species

Both of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Honduras has adopted the FSIS regulatory requirements for *Salmonella* testing. The *Salmonella* testing programs were found to meet the basic FSIS regulatory requirements.

At the time of this audit, Honduras was not exempt from the species verification testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

MONTHLY REVIEWS

These reviews were being performed by the Honduran equivalent of Circuit Supervisors. All were veterinarians with experience. Dr. Francisco Ordonez was in charge of these reviews

The internal review program was applied equally to both export and non-export establishments. Internal review visits were announced in advance and were conducted by individuals, at least once monthly, and sometimes more often. The records of audited establishments were kept in the inspection offices of the individual establishments. In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, a supervisor is empowered to conduct an in-depth review, and the results are reported to SENASA for evaluation; they formulate a plan for corrective actions and preventive measures to be completed before relistment.

After observing the internal reviewers' activities in the field, the auditor was confident in their professionalism, thoroughness, and knowledge of U.S. requirements, and in the effectiveness of Honduras' internal review program as a whole.

Enforcement Activities

On 15 Feb 2000, new laws were enacted to join domestic and export rules and regulations and make them the same. Also see enclosed attachment of recent enforcement cases. They are in Spanish and will need to be translated for perusal.

EXIT MEETING

An exit meeting was conducted in Tegucigalpa on March 28, 2000. The Honduran participants were; Dr. Francisco Rodas, Sub-Director of SENASA; Dr. Perdo Mendoza, Chief of SIOPOA; Dr. Alberto Cruz, National Supervisor of SIOPOA; Dr. Pedro Barahona, Chief of Meat Section of SIOPOA; Dr. Max Rivera, Director of Laboratory, ANEDEC; Mr. Omar Gonzales, Agriculture U.S. Embassy; Ms. Gloria DeGuzman, Translator and Dr. M. Douglas Parks, International Auditor USDA. The following topics were discussed:

1. The results of the on-site audits. All Honduran officials gave assurances that the deficiencies found in the establishments would be corrected to satisfactory level and done immediately. The following deficiencies were corrected on-the-spot immediately:

Unmarked boxes for export and domestic sale.

Esophagi not completely split.

Residues in a grinder and a box.

Edible product tray on the floor.

Poor neck flap retention method.

Dripping condensation in a product trafficway.

The dressing procedure and the inspection procedure for tails was changed and intensified.

Other deficiencies were handled as follows:

The plans for *E. coli* and *Salmonella* testing will be revised to reflect the immediate changes that were put in place.

The plastic in the product investigation was started immediately.

The revisions necessary for the HACCP plan, more specific critical limits and limits for CCP #5, will be done as soon as possible.

The SSOP plan will be updated and signed very soon.

Both establishments were rated as acceptable.

- 2. The results of the laboratory audit: The findings were satisfactory.
- 3. The inspection force training program: adequate results.
- 4. The unanswered letters from Policy. They were re-sent to the embassy.
- 5. Compliance records: Satisfactory.

CONCLUSION

The inspection system of Honduras was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments

Two establishments were audited: both were acceptable. The deficiencies encountered during the on-site establishment audits, in those establishments which were found to be acceptable, were adequately addressed to the auditor's satisfaction.

Dr. M. Douglas Parks International Audit Staff Officer (Signed) Dr. M. Douglas Parks

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing.
- D. Data collection instrument for Salmonella testing

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

- 1. The establishment has a written SSOP program.
- 2. The procedure addresses pre-operational sanitation.
- 3. The procedure addresses operational sanitation.
- 4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
- 5. The procedure indicates the frequency of the tasks.
- 6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
- 7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
- 8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

	1.Written	2. Pre-op	3. Oper.	4. Contact	5. Fre-	6. Respons-	7. Docu-	8. Dated
	program	sanitation	sanitation	surfaces	quency	ible indiv.	mentation	and signed
Est.#	addressed	addressed	addressed	addressed	addressed	identified	done daily	
4		$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$		V	$\sqrt{}$
12		$\sqrt{}$			$\sqrt{}$			no

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

- 1. The establishment has a flow chart that describes the process steps and product flow.
- 2. The establishment had conducted a hazard analysis.
- 3. The analysis includes food safety hazards likely to occur.
- 4. The analysis includes the intended use of or the consumers of the finished product(s).
- 5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
- 6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
- 7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
- 8. The plan describes corrective actions taken when a critical limit is exceeded.
- 9. The HACCP plan was validated using multiple monitoring results.

Est.#	diagram	ard an-	3. All ident-	4. Use includ-	5. Plan hazard	for all	7. Mon- is spec-	8. Corr.	9. Plan ted	quate proced-	11.Ade- docu-	ed and
4	√	√	√	√	√	√	No	V	V	√	tion √	√
12	√	V	V	V	V	V	No	V	V	V	V	√

Data Collection Instrument for Generic E. coli Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

- 1. The establishment has a written procedure for testing for generic E. coli.
- 2. The procedure designates the employee(s) responsible to collect the samples.
- 3. The procedure designates the establishment location for sample collecting.
- 4. The sample collection is done on the predominant species being slaughtered.
- 5. The sampling is done at the frequency specified in the procedure.
- 6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
- 7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
- 8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
- 9. The results of the tests are being recorded on a process control chart showing the most recent test results.
- 10. The test results are being maintained for at least 12 months.

Γ		1.Writ-	2. Samp-	3.Samp-	4. Pre-	5. Samp-	6. Pro-	7. Samp-	8. Using	9. Chart	10. Re-
		ten pro-	ler des-	ling lo-	domin.	ling at	per site	ling is	AOAC	or graph	sults are
	Est. #	cedure	ignated	cation	species	the req'd	or	random	method	of	kept at
				given	sampled	freq.	method			results	least 1 yr
	4	V	V	no	V	V	V	V	V	V	V
	12	\checkmark	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	\checkmark	\checkmark	$\sqrt{}$		$\sqrt{}$	$\sqrt{}$

Data Collection Instrument for Salmonella testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

- 1. Salmonella testing is being done in this establishment.
- 2. Carcasses are being sampled.
- 3. Ground product is being sampled.
- 4. The samples are being taken randomly.
- 5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.
- 6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

	Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
Ī	4	$\sqrt{}$	√	N/A	√	√	√
Ī	12	V	V	N/A	No	√	V

13